U.S. FOOD & DRUG ADMINISTRATION

# Elana Surgical Kit
# H080005

Presentation to the Pediatric Advisory Committee
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# ANNUAL UPDATE

- We are unaware of sales or use of this device since the last PAC meeting
- There have been no Medical Device Reports (MDR) associated with this device
- There have been no new scholarly publications since the last PAC meeting

# CONCLUSIONS

- FDA's Review Team has identified no new safety concerns since September 2016's PAC meeting
- FDA concludes that the probable benefit/risk profile of the device for the pediatric population continues to support the HDE
- The Mandated Post-Approval Study has been put on hold due to non use in the United States. Should device use resume, the study will be reinstated

# FDA Recommendations

FDA will continue surveillance and report the following to the PAC in 2018:

- Annual Distribution Number (ADN)
- MDR Review
- Literature Review
- Mandated Post-Approval Study Review

# Question to the PAC

Does the Committee agree with FDA's conclusions and proposed approach?


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